DEC 1 9 2001

K012199

XII. SAFE MEDICAL DEVICES ACT OF 1990 SUMMARY OF SAFETY AND EFFECTIVENESS. Sept. 10, 1996. [Separate Pages]

I.* Submitter: Dr. Syed Rizvi, Humana USA, Inc., Reno, Nevada. Ph: 661-761-9771.

II. Classification Names and Numbers: Accessory to surgeon's gloves, KGO.

III. Common/Usual Name: Accessory to Surgeon's gloves.

IV. Proprietary Names: DigiCAP™

V. Establishment Registration Number: In progress

VI. Classification: Surgeon's gloves were classified by the General and Plastic Surgery Panel under CFR 878.4460 and are Class I, restricted.

VII. Substantial Equivalence: The DigiCap™ is an accessory to surgeon's gloves, Code HGO, and is equivalent to the many surgeon's gloves cleared under the 510(k) process and is most similar to the "Gimbel Puncture Resistant Powder Free Surgical Glove cleared under K003063. It is also similar to the Percuguard cleared under K992539 but differs from it in that the Percuguard is intended for use with an examination glove during injection and examination activities while the DigiCap is intended for use by surgeons during various surgical procedures.

The "510(k) "Substantial Equivalence" Decision-Making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed as described below:

1. These products have the same intended use, to provide protection of the patient and surgeon from blood contamination and to reduce needle-sticks and scalpel cuts during surgical procedures. Both provide a tough, repellant surface to protect the fingers of surgical personnel. Since the DigiCAP is on the outside of the glove, it also protects the integrity of the glove to body fluids.

2. The technological characteristics for this product are similar to those for the predicate devices and similar products currently on the market. This product, however, is made from a polycarbonate resin and is of a rigid configuration whereas surgeons gloves are usually prepared from latex or vinyl materials. All materials are tested for biocompatibility.

3. Descriptive information provided shows that the materials from which the DigiCAP is made provide the protection claimed and are substantially equivalent in safety and effectiveness to those of similar products, used for similar purposes, currently on the market.

4. The FDA "Decision-Making Process" chart was also used and appears in Attachment V.

[End of Summary]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 9 2001

Humana USA, Incorporated
C/O Dr. H.N. Dunning
Dr. H.N. Dunning
8309 Bryant Drive
Bethesda, Maryland 20817

Re: K012199
Trade/Device Name: Digicap
Regulation Number: 878.4460
Regulation Name: Needle Accessory
Regulatory Class: I
Product Code: KGO
Dated: October 30, 2001
Received: November 5, 2001

Dear Dr. Dunning:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

VIII.1 Indications for Use: [Separate Page]

510(k) Number: K012199

Device Name: DigiCAP™

DigiCap™ is a protective finger guard accessory to the surgeon's glove.

1. Intended to provide needlestick and suture/scalpel protection during a variety of surgical procedures. DigiCap™ is a protective finger guard accessory to the surgeon's glove. It is used on the finger or thumb of the non-dominant hand usually used to retract, stabilize, compress, and position tissue during surgical procedures.

2. Facilitate suture handling and placement.

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use____
(Per 21 CFR 801.109) (Optional format 1-2-96)

Chien S. Lin 3R

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012199